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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/597,935	09/07/2007	Stefano Fais	113-06	8086
23713 7590 04/19/2011 GREENLEE SULLIVAN P.C. 4875 PEARL EAST CIRCLE SUITE 200 BOULDER, CO 80301			EXAMINER GREENE, IVAN A	
			ART UNIT 1619	PAPER NUMBER
			MAIL DATE 04/19/2011	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary**

Application No.

10/597,935

Applicant(s)

FAIS ET AL.

Examiner

IVAN GREENE

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01/28/2011.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 50-76 is/are pending in the application.
- 4a) Of the above claim(s) 50 and 59-76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>01/26/2011</u>  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### **Status of the Claims**

Claims 50-76 are pending. Claims 1-49 have been previously canceled by applicant. Claims 50 and 59-76 have been withdrawn based upon a requirement for restriction dated, 08/02/2010. Claims 51-58 are being examined herein.

Applicant's claim amendments to the claims, filed 01/28/2011, incorrectly list claim 58 as being withdrawn. The Non-Final office action dated 10/28/2010 clearly indicated that claims 51-58 read on applicant's elected species and examined claims 1-58 (see p. 3, line 8; and statements of rejection on pages 4, 7 & 8). Any response the instant office action should include a corrected claim listing with proper claim identifiers for each claim or such response will be held as noncompliant.

### **Advisory Notice**

All rejections and/or objections not explicitly maintained in the instant office action have been withdrawn per Applicants' claim amendments and/or persuasive arguments.

### **Priority**

The U.S. effective filing date has been determined to be 02/14/2005, the filing date of the international application PCT/EP2005/002250.

### **Information Disclosure Statement**

The information disclosure statement(s) submitted on 04/06/2011 was filed after the mailing date of the first office action on the merits, however, applicant has paid the \$180 fee.

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The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement has been considered by the Examiner.

### **Objection to the Specification**

#### **Response to Arguments:**

Applicant's submission of an amended title for the instant application, filed 01/28/2011, is acknowledged. However, the amended title appears to be in error because the word "Proton" has been replaced with the word "Protein". The instantly claimed invention is drawn to a therapeutic composition of matter comprising a proton pump inhibitor. The following title has been suggested as a replacement title: Method of using proton pump inhibitors in combination with other medicaments. In view of the apparent error, the instant objection is maintained. Appropriate correction is required.

### **Claim Rejections**

#### **Claim Rejections - 112 2<sup>nd</sup>**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**New grounds of rejection necessitated by amendment: Claims 51-58 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps required to perform the invention. See MPEP § 2172.01.**

The omitted structural cooperative relationships are: a correlation step in the body of independent claim 51 to effect the purpose recited in the preamble of the claims, namely a method of treatment of a cancerous condition which causes an acidic microenvironment. Adding a statement to the end of claim 51 to the effect: "thereby effectively treating the cancerous condition which causes an acidic microenvironment" is suggested. Claims 52-57 are rejected as depending from rejected claim 51.

### **Claim Rejections - 35 U.S.C. 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Rejection maintained: Claims 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by SARTORI (Journal of Clinical Oncology, Vol. 18, No. 3, pp. 463-467; published February 2000).**

### **Response to Arguments:**

Applicant's arguments filed 01/28/2011 have been fully considered but they are not persuasive.

Applicant's amendment of independent claim 51 to require the patient is "a cancer patient", is acknowledged. However this amendment does nothing to overcome the above rejection over SARTORI because the active method step of "oral administration of a therapeutic method of treatment utilizing a composition comprising a PPI to a cancer patient in need thereof"

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is anticipated by SARTORI because SARTORI discloses the oral administration of a PPI to cancer patients. As the method step, pharmaceutical composition, and patient class are coextensive, the result would have been the same (i.e. treatment of a cancerous condition). In fact, as currently drafted, independent claim 51 reads on any cancer patient taking an oral proton pump inhibitor such as PRILOSEC® (omeprazole).

### **Claim Rejections - 35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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**Rejection maintained: Claims 56-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over SARTORI as applied to claims 51-55 above, and PHILLIPS (US 20030191159, 9 October 2003, benefit to 19 January 2002; issued as US 6,699,885; 2 March 2004, benefit to 19 January 2002).**

**Response to Arguments:**

Applicant's arguments filed 01/28/2011 have been fully considered but they are not persuasive.

Applicant's argument that "Neither Sartori nor Phillips discloses or suggests that proton pump inhibitors, either alone or in combination with other compounds, would be useful to treat cancerous conditions" (p. 9, lines 12-13), is not convincing because the reference SARTORI discloses the step of oral administration of a therapeutic composition comprising a proton pump inhibitor to a cancer patient, and Phillips suggests a methods of administering pharmaceutical composition comprising a proton pump inhibitor (omeprazole) and calcium carbonate (i.e. an antacid drug). And as the method step, pharmaceutical composition, and patient class are coextensive, the result would have been the same (i.e. treatment of a cancerous condition).

Applicant's argument that "[a person having ordinary skill in the art to which the invention pertains] would not be motivated to combine the teachings of the two cited documents which are from different technical fields, Sartori relating to the prevention of chemotherapy-side effects, while Phillips relates to the treatment of acid-related disorders such as ulcers and reflux, not related to chemotherapy side effects" (p. 9, lines 14-17), is acknowledged. In response the

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examiner argues that the reference SARTORI and the reference PHILLIPS each administer a PPI orally. The orally administered PPI in the invention of SARTORI inhibits gastric acid secretion as a means of preventing chemotherapy induced gastroduodenal mucosal injury (SARTORI: col. 1, lines 17-19). And the orally administered PPI in the invention of PHILLIPS inhibits gastric acid secretion thereby treating gastric acid disorders (PHILLIPS: [0004] & [0040]). Accordingly, each of SARTORI and PHILLIPS disclose methods for the treatment of gastric disorder by oral administration of a PPI, the same technical field of invention. The cause of the gastric disorder contemplated by each of the references differs, but the method of administration (i.e. oral) and the drug (i.e. a PPI) are the same. Accordingly, applicant's argument that a person having ordinary skill in the art to which the invention pertains would not be motivated to combine the teachings of the two cited documents, is not convincing.

Applicant's argument that "if [a person having ordinary skill in the art to which the invention pertains] were to combine these documents, they would not arrive at a method of treating cancer comprising administering proton pump inhibitors because neither document suggest that proton pump inhibitors themselves are effective against cancer" (p. 9, lines 18-21), is acknowledged. In response the examiner argues that SARTORI discloses the step of oral administration of a therapeutic composition comprising a proton pump inhibitor to a cancer patient, and because the method step, pharmaceutical composition, and patient class are coextensive, the result would have been the same (i.e. treatment of a cancerous condition).

Applicant's argument that "the combination of commercially available proton pump inhibitors (e.g., omeprazole) and antacids (e.g. TUMS), which again are known in combination for the treatment of such problems as acid indigestion, but not cancer" (p. 9, lines 29-31), is



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acknowledged. In response the examiner argues that the reference SARTORI clearly discloses an overlap in the patient class of cancer patients with patients suffering from acid indigestion (i.e. chemotherapy induced gastroduodenal mucosal injury). Accordingly, applicant's argument regarding the class of patients being treated is not convincing.

### **Conclusion**

Claims 51-58 have been examined on the merits. Claims 51-58 are rejected under 35 U.S.C. 112, first paragraph; claims 51-55 remain rejected under 35 U.S.C. 102(b); and claims 56-58 remain rejected under 35 U.S.C. 103(a). No claims allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IVAN GREENE whose telephone number is (571)270-5868. The examiner can normally be reached on Monday through Friday 7AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Blanchard can be reached on (571) 272-0827. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

IVAN GREENE  
Examiner, Art Unit 1619

/CHERIE M WOODWARD/  
Primary Examiner, Art Unit 1647